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Inventors: ITO et al.
Serial No.: 10/531,433
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REMARKS

Claims 1-17 are pending in the instant application. Claims 1-17 have been rejected. Claim 1 has been amended to correct a typographical error. New claims 18-20 have been added. Support for these amendments is provided at page 13 of the specification. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Amendments to Specification

The specification has been amended to include at page 1, following the title, the priority claim as set forth in the Declaration and first Filing Receipt issued by the USPTO

In addition, Table 1 on page 19 of the specification has been amended to state a Liquid Paraffin percentage of 5.0. Support for this amendment is provided in the specification at page 13, line 12 of Example 1.

No new matter is added by these amendments and entry is respectfully requested.

II. Rejection under 35 U.S.C. § 103

Claims 1-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,814,032 issued to Hori et al. ("Hori").

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Applicants respectfully his rejection as the combination of Hori with the knowledge of one having skill in the art fails to disclose, suggest, or predict the patch recited in claim 1.

Hori generally teaches a pressure-sensitive adhesive tape layer that primarily includes an elastomeric portion, a hygroscopic material, and a drug - all in an attempt to provide good attachment to a skin surface even in the case of water permeation after attachment, and easy detachment so that part of the hygroscopic material remains on the attachment surface. To achieve these goals, Hori presents several mostly indiscriminate lists of (1) at least 3 preferable elastomers, (2) at least 13 hygroscopic materials, (3) at least 121 drugs of "no particular restriction", and (4) at least 80 absorption accelerators (of which Hori prefers, among others, bromine- or chlorine-substituted aliphatic hydrocarbons, which do not include mineral oils such as liquid paraffin).

The sheer number of possible combinations and proportions accordingly refutes the Examiner's position that claim 1 is a result of routine experimentation, which is itself of dubious validity. See, e.g., *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1366 (Fed. Cir. 2007)

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("[R]eference to "routine testing" or "routine experimentation" is disfavored. See, e.g., *In re Yates*, 663 F.2d 1054, 1056 n.4 (C.C.P.A. 1981) ("The Solicitor . . . argues that it is 'not unobvious to discover optimum or workable ranges by routine experimentation.' In many instances, this may be true. The problem, however, with such 'rules of patentability' (and the ever-lengthening list of exceptions which they engender) is that they tend to becloud the ultimate legal issue—obviousness—and exalt the formal exercise of squeezing new factual situations into preestablished pigeonholes. Additionally, the emphasis upon routine experimentation is contrary to the last sentence of section 103.") (internal citation omitted); *In re Saether*, 492 F.2d 849, 854 (C.C.P.A. 1974) ("In his argument that 'mere routine experimentation' was involved in determining the optimized set of characteristics, the solicitor overlooks the last sentence of 35 U.S.C. § 103 Here we are concerned with the question of whether the claimed invention would have been obvious at the time it was made to a person having ordinary skill in the art—not how it was achieved.") (internal citation omitted); *In re Fay*, 347 F.2d 597, 602 (C.C.P.A. 1965) ("[W]e do not agree that 'routine experimentation' negatives patentability. The last sentence

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of section 103 states that 'patentability shall not be negatived by the manner in which the invention was made.' To support the board's decision that 'routine experimentation within the teachings of the art' will defeat patentability requires a primary determination of whether or not appellants' experimentation comes within the teachings of the art. Whether the subsequent experimentation is termed 'routine' or not is of no consequence.").

Further examination of Hori's teachings indicates that from among the many possible combinations and proportions of these elements, claim 1 would not be obvious to try or properly regarded as being available through "routine experimentation". First, fentanyl, though mentioned almost as an after thought at the end of a list including at least 120 drugs, is never used in specific combination with any elastomer or absorption accelerator, especially not either PIB or mineral oil.

What is more, although recited within its lists of elastomers and absorption accelerators, Hori never specifically prepares any tape containing PIB and mineral oil. This is because Hori specifically teaches away from the combination of PIB and mineral oil, especially as found in the proportions of claim 1. Hori's Examples 1-14 contain

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relatively small proportions of elastomer (50-70 parts), while Comparative Examples 1-5 of Hori (made to represent undesirable characteristics) have higher amounts of elastomer (87-90 parts). Hori's Examples 1-14, each of which contain no more than 70% elastomer, are all shown to exhibit low skin irritation. By contrast, Comparative Examples 1-5, each of which contain more than 70% elastomer, are the only ones to exhibit unfavorable results as for skin irritation. See Table 2. This might provide for amounts of elastomer at least as low as 70 parts by weight, but it certainly teaches away from using any particular tape that uses more than 70 parts by weight elastomer. A skilled person would have accordingly been led away from combining 75.2-94% (or as in new claim 18, 85-93%) of any elastomer in any tape, let alone one specifically including PIB.

Hori also teaches away from attempting a specific combination of more than 70% PIB with (1) mineral oil, (2) mineral oil in an amount equal to between .25 to .05 parts based on the amount of PIB, or (3) mineral oil optionally used in conjunction with one or more other absorption enhancers. Hori fails to suggest or predict a tape - any tape - having mineral oil. Hori specifically teaches the inclusion of 80 absorption accelerators, 36 of which include

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aliphatic hydrocarbons that preferably have a bromine- or chlorine-substituted group. Nowhere does Hori, however, disclose a particular tape having a mineral oil such as paraffin.

In fact, out of the at least 36-member aliphatic hydrocarbon subset of Hori's at least 80 member list of potential absorption accelerators, Hori prefers 6 bromine- or chlorine-substituted aliphatic hydrocarbons, which would have tended to exclude mineral oils (in this case paraffin) from serious consideration by one skilled in the art. Hori reinforces this exclusion by failing to indicate any preferred examples from within the other five absorption accelerator subsets, further reducing the attractiveness of paraffin as seen within the context of at least 80 accelerators. Hori in effect creates at least three classes of accelerators, (1) those that are preferable with a subclass, (2) those that are not preferable within a subclass, and (3) those that are neutral. In the mind of one having skill in the art and without benefit of hindsight, Hori accordingly ranks paraffin not only after the at least 6 preferable hydrocarbons in its own subset, but also after the 44 other neutrally listed absorption accelerators.

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Hori likewise fails to teach, suggest, or predict the proportion of mineral oil with respect to PIB as set forth in claim 1. While Hori allows adding paraffin "singly or as a mixture" of accelerators, it does not specify a proportion of the mineral oil. Rather, it is specific only in that the total amount of accelerator - be it a single accelerator or a mixture thereof - be .5 to 20 parts.

Hori similarly fails to recite what the proportion of mineral oil is with specific respect to PIB. Rather, Hori broadly states that the amount of total accelerator be set in proportion to the amount of total elastomers *and the hygroscopic material* (but not with respect to the elastomers alone or a particular elastomer). From among its virtually countless possible mixtures of elastomers, hygroscopic materials, and accelerators, Hori does nothing in the way of pointing to - and in fact points away from - the combination recited in claim 1. Hori therefore fails to suggest or predict, by optimization or otherwise, .25 to .05 parts mineral oil to PIB as recited in claim 1. Its teachings are to the contrary.

In regard to claims 5 and 6, Hori expresses the total amount of accelerators "singly or as a mixture", but nowhere does it teach a particular amount of mineral oil or a

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particular mixture of mineral oil and enhancer such as isopropyl myristate. As mentioned above, paraffin's remarkably low position on Hori's list of at least 80 absorption accelerators makes its selection for a mixture with another absorption accelerator unlikely.

Thus, it cannot be said that Hori would suggest or predict the particular components and ratios of claim 1 as being either available through routine experimentation or obvious to try. From among Hori's mostly indiscriminate lists of (1) at least 3 preferable elastomers, (2) at least 13 hygroscopic materials, (3) at least 121 drugs of "no particular restriction", and (4) at least 80 absorption accelerators (of which Hori prefers bromine- or chlorine-substituted aliphatic hydrocarbons, not including mineral oil or liquid paraffin), sufficient reason to try the combination of elements in claim 1 does not exist. There are simply too many combinations of these components to arrive at the particular mixture of claim 1. See *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs., Inc.*, No. 2007-1223, slip op. at 9 (Fed. Cir. Mar. 31, 2008) ("Moreover this invention, contrary to Mylan's characterization, does not present a finite (and small in the context of the art) number of options easily traversed to show obviousness. The

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passage above in KSR posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness. In this case, the record shows that a person of ordinary skill would not even be likely to start with 2,3:4,5 di-isopropylidene fructose (DPF), as Dr. Maryanoff did. Beyond that step, however, the ordinarily skilled artisan would have to have some reason to select (among several unpredictable alternatives) the exact route that produced topiramate as an intermediate.").

This conclusion is made especially true when we consider that all of Hori's examples using more than 70 parts elastomer (Comparative Examples 1-5) defeat Hori's disclosed purpose of preventing skin irritation. Thus, these five examples are actually used as comparative examples of what not to use, and accordingly teach away from the combination of greater than 70% PIB found in claim 1. Also dispositive to the question of obviousness is Hori's teachings against a combination of more than 70% PIB with (1) mineral oil, (2) mineral oil in an amount equal to between .25 to .05 parts based on the amount of PIB, or regarding claim 5, (3) mineral oil used in conjunction with one or more other absorption enhancers.

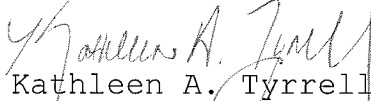
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Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of all pending claims is earnestly solicited.

Respectfully submitted,


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